Federal AIDS Policy Partnership (FAPP) Research Working Group (RWG)
Meeting with Dr. Fauci re: DAIDS RFA FY '06 Draft Concept
March 9, 2004

The focus of the meeting is as follows:

Issues to be considered:

- Applicability
  - "Optimal" therapies ←→ cost effective and deliverable interventions
  - Timelines – learn as much as possible from each trial (slower, resource intensive ←→ less slow and focused).
- Individual RCT ←→ community RCT
- Individual recruitment ←→ family focus
- Domestic ←→ international 'agenda'
- "Long term clinical outcome ←→ "surrogate markers"
- Routes of exposure – vaginal, rectal, perinatal (peripartum, breastfeeding), parenteral, oral
- Ages – adults, adolescents, newborns, perinatal
- Focus?

Stop New Infections:

- Protect the uninfected – Develop HIV vaccines, microbicides, therapies/vaccines, behavior and barrier methods.
- Reduce infectiousness of HIV infected – Reduce viral load and/or shedding, modify transmission events
- Vaccines
  - 2-3 efficacy trials; impact on infection, disease progression and secondary transmission (RCT and also community based).
  - Selection and improvement (selection of most promising candidates and continued improvement in vaccine design).
- Passive transfer in MTCT – Selection of best possible combinations for "proof of concept" in MTCT setting.
- Microbicides – Adherence and selection of control arm(s)
- Science – 1-2 phase III trials (RCT, Placebo vs. condom-only arm as comparison)
- Behavior (individual, community)
- Barriers (male vs. female)
- Treatments (ART, Co-infections)
- Vaccines (HPV?)

Keep Infected Persons Healthy:

- When to start and with what; when to switch
  - Early initiation or deferred therapy
  - Adherence, cost-benefit, drug conservation
- Resistance and salvage
  - Sequencing regimens to retard resistance

    - New approaches for highly treated – new treatments
- Immune preservation or restoration
    - Immune modulation to augment lymphocyte number or function
    - "Therapeutic" vaccines
- Co-infections/Concomitant Meds
    - Tuberculosis
    - Hepatitis – B, C and GBVc
    - Malaria
    - Natural products
- Reduce or control complications
    - Managing CV, GI and neuro signs and sx
    - Developing new drug regimens
- Simplify diagnosis, monitoring, delivery

Examples of Coordinated Science:

- Common trials – single trial jointly planned and conducted (AVEG/HPTN phase II trial)
- Simultaneous trials (HPTN052, AACTG 5175, AACTG 5190)
- Trials conducted in the same setting
- Data sharing
- Impact of prevention and ART on transmission
- Treatment of HIV+ women in resource-limited/developing countries and impact on MTCT
- Treatment and prevention vaccine research
- Studies of acute infection; viral dynamics; reservoirs (Vaccines, Rx, microbicides)
- Cross-cutting lab research (diagnosis, immune assays, endpoint monitoring)
- Cross-cutting background issues (nutrition, traditional therapies, endemic infections)

Participant List:

Judith Auerbach
Huntly Collins
Lynda M. Dee
Gregg Gonsalves
Mark Harrington
Polly Harrison
Jeanne Ireland
Anthony Fauci
Jack Whitescarver
NIAID KC